



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mai H. Nguyen  
Serial No.: 09/901,339  
Filed: July 9, 2001  
Docket: 30448.73USU1  
Title: METHODS FOR DIAGNOSING BREAST CANCER USING NIPPLE FLUID

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CERTIFICATE UNDER 37 CFR 1.8

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By:   
Name: Richelle Ann Domingo

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

We are transmitting herewith the attached:

- ☒ Transmittal sheet, in duplicate, containing Certificate under 37 CFR 1.8.
- ☒ Information Disclosure Statement (37 C.F.R. §1.97 (d))
- ☒ Form 1449 (Information Disclosure Statement) (2 sheets)
- ☒ Exhibits 1 - 20
- ☒ Return postcard

Please charge any additional fees or credit overpayment to Deposit Account No. 50-0306. A duplicate of this sheet is enclosed.

**MANDEL & ADRIANO**

35 No. Arroyo Parkway, Suite 60  
Pasadena, California 91103  
(626)395-7801

By: 

Name: SaraLynn Mandel  
Reg. No.: 31,853  
Initials: SLM  
Customer No. 26,941

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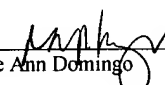
**Applicant:** Mai H. Nguyen  
**Serial No.:** 09/901,339  
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**Title:** METHODS FOR DIAGNOSING BREAST CANCER USING NIPPLE FLUID

**Examiner:** Not Yet Known  
**Group Art Unit:** 1743  
**Docket No.:** 30448.73USU1

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By:   
Richelle Ann Domingo

**INFORMATION DISCLOSURE STATEMENT**

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Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. They are as follows:

- U.S. Patent No. 5,187,062, 16 February 1993, Sato et al. (Exhibit 1)
- Cheales-Siebenaler, Noreen J., "Induced Lactation in an Adoptive Mother," *Journal of Human Lactation*, March 1999, 15(1):41-3. (Exhibit 2)
- Foretova, Lenka et al., "Carcinoembryonic Antigen in Breast Nipple Aspirate Fluid," *Cancer Epidemiology, Biomarkers and Prevention*, March 1998, 7:195-8. (Exhibit 3)
- Fujimoto, Kiyohide et al., "Increased Serum Levels of Basic Fibroblast Growth Factor in Patients with Renal Cell Carcinoma," *Biochemical and Biophysical Research Communications*, October 15, 1991, 180(1):386-92. (Exhibit 4)

- Gail, Mitchell H. et al., "Projecting Individualized Probabilities of Developing Breast Cancer for White Females Who Are Being Examined Annually," *Journal of the National Cancer Institute*, December 20, 1989, 81(24):1879-86. (Exhibit 5)
- Gann, Peter et al., "Mitogenic Growth Factors in Breast Fluid Obtained from Healthy Women: Evaluation of Biological and Extraneous Sources of Variability," *Cancer Epidemiology, Biomarkers and Prevention*, June 1997, 6(6):421-8. (Exhibit 6)
- Li, Vincent W. et al., "Microvessel Count and Cerebrospinal Fluid Basic Fibroblast Growth Factor In Children With Brain Tumours," *Lancet*, July 9, 1994, 344:82-6. (Exhibit 7)
- Lin, Richard Y. et al., "Diagnostic and Prognostic Role of Basic Fibroblast Growth Factor in Wilms' Tumor Patients," *Clinical Cancer Research*, March 1995, 1:327-31. (Exhibit 8)
- Nguyen, Mai, "Angiogenic Factors as Tumor Markers," *Investigational New Drugs*, 1997, 15:29-37. (Exhibit 9)
- Nguyen, Mai et al., "Elevated Levels of an Angiogenic Peptide, Basic Fibroblast Growth Factor, in the Urine of Patients with a Wide Spectrum of Cancers," *Journal of National Cancer Institute*, March 2, 1994, 86(5):356-61. (Exhibit 10)
- O'Brien, T.S. et al., "Urinary Basic Fibroblast Growth Factor in Patients with Bladder Cancer and Benign Prostatic Hypertrophy," *British Journal of Urology*, 1995, 76:311-4. (Exhibit 11)
- Petrakis, Nicholas L., "Nipple Aspirate Fluid in Epidemiologic Studies of Breast Disease," *Epidemiologic Reviews*, 1993, 15(1):188-95. (Exhibit 12)

- Rose, David P., "Hormones and Growth Factors in Nipple Aspirates from Normal Women and Benign Breast Disease Patients," *Cancer Detection and Prevention*, 1992, 16(1):43-51. (Exhibit 13)
- Sauter, Edward R. et al., "Prostate-Specific Antigen Levels in Nipple Aspirate Fluid Correlate with Breast Cancer Risk," *Cancer Epidemiology, Biomarkers and Prevention*, December 1996, 5:967-70. (Exhibit 14)
- Sluitz, G. et al., "Serum Evaluation of Basic Fibroblast Growth Factor in Cervical Cancer Patients," *Cancer Letters*, 1995, 94(2):227-31. (Exhibit 15)
- Takei, Yoshifumi et al., "Serum Concentrations of Basic Fibroblast Growth Factor in Breast Cancer," *Clinical Chemistry*, 1994, 40(10):1980-1. (Exhibit 16)
- Watanabe, H. et al., (Abstract) "Basic Fibroblast Growth Factor in Human Serum – A Prognostic Test for Breast Cancer," *Molecular Biology of the Cell (formerly Cell Regulation) Abstracts*, September 1992, 3:234a. (Exhibit 17)
- Watanabe, Hiroyuki et al., "A Sensitive Enzyme Immunoassay for Human Basic Fibroblast Growth Factor," *Biochemical and Biophysical Research Communications*, February 28, 1991, 175(1):229-35. (Exhibit 18)
- Wrensch, Margaret et al., "Breast Cancer Risk Associated with Abnormal Cytology in Nipple Aspirates of Breast Fluid and Prior History of Breast Biopsy," *American Journal of Epidemiology*, April 15, 1993, 137(8):829-33. (Exhibit 19)

- Wensch, Margaret R. et al., "Factors Associated with Obtaining Nipple Aspirate Fluid: Analysis of 1428 Women and Literative Review," *Breast Cancer Research and Treatment*, 1990, 15:39-51. (Exhibit 20)

This statement should be considered because it is submitted before the mailing date of the first Office Action on the merits. In accordance with 37 C.F.R. §1.98(a)(2), copies of each document or other information listed on the enclosed Form 1449 are provided.

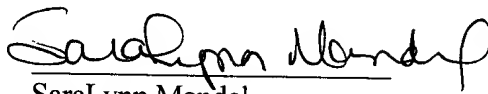
No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that the references have been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Mai H. Nguyen  
Serial No. 09/901,339  
Filed: July 9, 2001  
Page 5

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-0306.

Respectfully submitted,

A handwritten signature in cursive script, reading "SaraLynn Mandel". The signature is written in dark ink and is positioned above the printed name.

SaraLynn Mandel  
Registration No. 31,853  
Sarah B. Adriano  
Registration No. 34,470  
Attorney for Applicants  
Mandel & Adriano  
35 No. Arroyo Parkway, Suite 60  
Pasadena, California 91103  
(626)395-7801  
Customer No. 26,941

FORM 1449\*

INFORMATION DISCLOSURE STATEMENT  
IN AN APPLICATION

(Use several sheets if necessary)

Docket Number

30448.73USU1

Application Number

09/901,339

Applicant

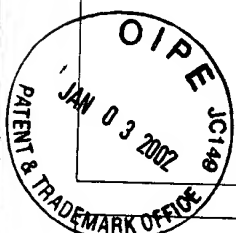
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Filing Date

July 9, 2001

Group Art Unit

1743



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U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	5,187,062 (Exhibit 1)	February 16, 1993	Sato et al.			JAN 08 2002

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FOREIGN PATENT DOCUMENTS

DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
					YES NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Cheales-Siebenaler, Noreen J., "Induced Lactation in an Adoptive Mother," <i>Journal of Human Lactation</i> , March 1999, 15(1):41-3. (Exhibit 2)
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EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

\*Substitute Disclosure Statement Form (PTO-1449)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

FORM 1449\*

Sheet 2 of 2

# INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION

(Use several sheets if necessary)

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Applicant

Mai H. Nguyen

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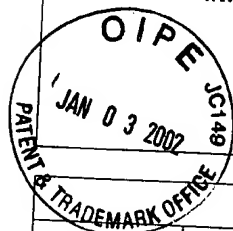
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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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